



APR 17 2009

47224 Mission Falls Ct.
Fremont, CA 94539
510-360-7523
info@viopix.com

SUMMARY

Submitter's name: ViOptix, Inc.
Address: 47224 Mission Falls Ct.
Fremont, CA 94539
Phone: 510-360-7523
Fax number: 510-226-5864
Name of contact person: Grace Holland
Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411

Date the summary was prepared: March 13, 2009

Name of the device: VesseLink Microvascular Anastomotic
Coupler System
Classification name: Microvascular Anastomotic Coupler
Product code: MVR
Device Class: 878.4300

The legally marketed device to which we are claiming equivalence
[807.92(a)(3)]:

Reference #	Device Name	Applicant
K040163	Microvascular Anastomotic Device	Synovis Micro Companies

Description of the device:

The VesseLink Microvascular Anastomotic Coupler (VesseLink) is a mechanical method for anastomosis, or connection, of small vessels ranging in size from 0.8 mm to 4.3 mm in outer diameter. The VesseLink is intended for use in the end-to-end and end to side vessel anastomosis as well as arterial/venous

vein grafts. It is to be used in veins and arteries that are normally encountered in microsurgical and vascular reconstructive procedures. Excluded is the use for coronary artery anastomosis.

Indications:

To be used in the anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. Excluded is the use for coronary artery anastomosis.

Summary of the technological characteristics of our device compared to the predicate device:

Technological Characteristics

This proposed device has the same technological characteristics as the predicate device.

Indications for Use

The Indications for Use for this proposed device had the same Indications for Use as the predicate device.

Performance Testing

Bench testing was performed to demonstrate the product functions as intended and is shown to be substantially equivalent.

CONCLUSION

Based on the design, technology, performance, functional testing, and intended use, the VesseLink is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. The VesseLink raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of VesseLink.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ViOptix, Inc.
% Regulatory Specialist, Inc.
Ms. Grace Holland
3722 Avenue Sausalito
Irvine, California 92606

APR 17 2009

Re: K090679

Trade/Device Name: Microvascular Anastomotic Coupler System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: MVR
Dated: March 13, 2009
Received: March 16, 2009

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

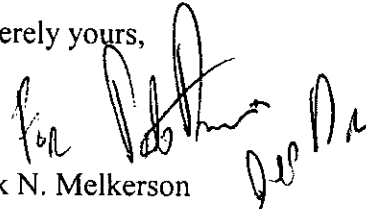
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K090679

Device Name: Microvascular Anastomotic Coupler System

Indications for Use:

The VesseLink is to be used in the anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. Excluded is the use for coronary artery anastomosis.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use ☐
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MVM
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K090679

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